1200 G Street NW, Suite 400
Washington, DC 20005–3814
Tel: 202 783 8700
Fax: 202 783 8750
www.AdvaMed.org

AdvaMed
Advanced Medical Technology Association

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: AdvaMed Comments submitted to Docket No. 2005D-0401 on Draft Guidance for Industry and FDA Staff: Compliance with Medical Device User Fee and Modernization Act of 2002, as amended – Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices

We understand comments submitted to the docket as well as recent discussions have raised questions about FDA's interpretation of the Medical Device User Fee Stabilization Act (MDUFSA) effective date requiring reprocessed single use devices to be marked with the name of the reprocessor or a generally recognized abbreviation or symbol of the reprocessor.

AdvaMed is the world's largest association representing manufacturers of medical devices, diagnostic products, and medical information systems. AdvaMed's more than 1,300 members and subsidiaries manufacture nearly 90 percent of the $80 billion of health care technology products purchased annually in the United States, and more than 50 percent of the $175 billion purchased annually around the world. AdvaMed members range from the largest to the smallest medical technology innovators and companies. More than 70 percent of our members have less than $30 million in domestic sales annually.

AdvaMed, will provide more detailed analysis on this issue in the near future but in the interim, AdvaMed wants to make clear its support for FDA's interpretation of the effective date as provided in FDA's draft guidance, titled "Compliance with Section 301 of the Medical Device User Fee and Modernization Act as amended – Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices." Section 502(u) of the Federal Food Drug and Cosmetic Act, as amended by the Medical Device User Fee Stabilization Act, requires manufacturers of reprocessed single devices to mark the reprocessed device prominently and conspicuously with the name of the reprocessor, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying the reprocessor. Section V.2.

of the FDA guidance document outlines the effective date for implementing the reprocessor labeling requirements of section 502(u). According to the guidance document, if the originalequipment manufacturer ("OEM") first marks a device with its name or symbol before August 1, 2006, the reprocessor must mark the reprocessed device by August 1, 2006; if the OEM first marks the device after August 1, 2006, the reprocessor must immediately mark the device using its own mark or an attachment prior to marketing the device.

The MDUFSA statutory language on the effective date is quite clear and only a plain reading of the statute accurately reflects Congressional intent as expressed in the Senate Report (109-107) accompanying MDUFSA. Specifically, the report states:

> ***"The committee believes it is essential to require the specific identification of reprocessed versions of single-use devices to ensure that physicians, nurses, users, and hospital administrators know that a device they have used was reprocessed."***

And

> ***"With respect to the marking requirement on single-use devices that the original manufacturer has not marked, the committee understands that some reprocessors should be able to implement this provision immediately. With respect to devices the original manufacturer has marked, the committee expects reprocessors to begin marking at least some of the devices they reprocess as soon as is feasible and to work expeditiously to mark all other reprocessed devices well before the 12-month deadline but in no case later than that deadline, in the best interest of post-market surveillance and the public health."***

Any other reading or interpretation of the effective date's statutory language would be nonsensical given the clear, expressed intent of the MDUFSA misbranding provision as articulated in the Senate Report.

In closing, AdvaMed intends to provide fuller and more detailed analysis on this in the near future. In the interim, and for the record, AdvaMed supports FDA's interpretation of the effective date as reflected in the draft guidance document and urges FDA to finalize the Guidance Document in its current form, which is consistent with the language of the statute and is in the best interest of public safety.

Sincerely,

Tara Federici

Tara Federici
Associate Vice President
Technology and Regulatory Affairs